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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,783	08/23/2006	Takao Okajima	280072US0PCT	3980
22850	7590	11/14/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MATTISON, LORI K	
			ART UNIT	PAPER NUMBER
			1619	
			NOTIFICATION DATE	DELIVERY MODE
			11/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,783	OKAJIMA ET AL.	
	Examiner	Art Unit	
	LORI MATTISON	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/04/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/21/2005; 11/16/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/2006, 1/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-8 are pending. Claims 1-5 are under examination as the elected Invention (Group I). This is the first Office Action on the merits.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement(s) (IDS) submitted on 01/20/2006 and 11/21/2006 were filed before the mailing date of the first action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the information disclosure statement is being considered by the examiner, except for those references lined through on the IDS(s) with the reason given.

Specification

Disclosure Objected To, Embedded Hyperlinks or Other Forms of Browser-Executable Code

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-5) in the reply filed on 09/04/2008 is acknowledged. The traversal is on the ground(s) that the Examiner has not provided any indication that the contents of the claims were interpreted in light of the description AND that claims 2-8 are dependent from instant claim 1.

The examiner has found both of applicant's arguments to be unpersuasive. With regard to the quoted Annex B, the determination of "special technical feature" is made on the contents of the claims as interpreted in light of the description and the drawings (if any)." The examiner utilized the contents of the instant claim to demonstrate that the "special technical features" were previously known in the art. No further interpretation was needed as applicant clearly claimed cleansing agents which harden when applied to the ear canal. As previously demonstrated by the examiner, these agents are known in the art and thus meet the limitations of the special technical feature recited in the instant claim 1.

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With regard to the dependency of claims 2-8, the MPEP (Chapter 1850, II Determination of “Unity of Invention”) explicitly states that, “The examiner should bear in mind that a claim may also contain a reference to another claim even if it is not a dependent claim as defined in PCT Rule 6.4. One example of this is a claim referring to a claim of a different category (for example, “Apparatus for carrying out the process of Claim 1 ...,” or “Process for the manufacture of the product of Claim 1 ...”). Similarly, a claim to one part referring to another cooperating part, for example, “plug for cooperation with the socket of Claim 1 ...”) is not a dependent claim.

In the instant case, instant claims 1-5 are drawn to a composition. Instant claim 6 contains a reference to instant claim 1 but is drawn to a different category (i.e. a method of using the body cavity cleansing agent). Similarly, instant claims 7 and 8 also contain a reference to instant claim 1 but drawn to a third category [i.e. an apparatus (a navel cavity opener)]. As taught by the MPEP, these are not dependent claims.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No 4,412,096 (hereinafter ‘096) by Edgerton et al, as evidenced by

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"Questions" from Abilene Speech & Hearing Center Copyrighted 2002 accessed 10/16/2008 from <http://www.abilenehearing.com/questions.htm>, "Protocol for Earmold Impressions" as prepared by LT Andy Hayes accessed 10/16/2008 from [http:// www-mcphc.med.navy.mil/occmed/ProtocolForTakingAnEarmoldImpressionAndyHayes.doc](http://www-mcphc.med.navy.mil/occmed/ProtocolForTakingAnEarmoldImpressionAndyHayes.doc), and US Patent No. 4891400 (hereinafter '400) by Schwabe *et al.*

Claim 1: The '096 prior art teaches an equivalent composition. The composition comprises of silicone material such as Promold or other flexible fast-setting silicones such as dental impression material or "Insta-Mold" brand silicone material (Col 4, lines 35-43). The silicone composition is mixed and applied to the ear canal (i.e. ear hole) of a patient. The composition cures and hardens (i.e. solidifies) and is removed from the patient's ear (Col. 4, lines 43-50). As evidenced by "Questions", taking impressions of the human ear canal is painless (page 7, paragraph 4) but the silicon molding material for ear molds is sticky and may stick to the skin, demonstrating that it will also adhere to dirt and other debris (such as cerumen) that is in the ear canal (page 7, paragraph 3). This assertion is further evidenced by "Protocol for Earmold Impressions," which describes how to make earmolds from silicone material, which explicitly states "Cerumen will adhere to the cured earmold impression....." (page 1, Patient Management Section, item 1). The examiner notes that cerumen (i.e. ear wax) entraps dirt which enters the ear canal. Hence, when the cured silicon ear mold is removed from the ear canal, with the cerumen is adhered to it, dirt is also removed. Thus, the ear mold is acting as a body cleansing agent through the removal of dirt and cerumen from the ear canal.

Claim 2: The limitations of instant claim 1 are addressed supra. The composition comprises of a silicone that has solidified. The solidified silicon material of the earmold of the '096 prior art is explicitly stated to be "flexible" and "elastic" demonstrating that it is a rubber (Col 1, lines 60-68; Col. 7, Claim 1). With regard to the composition having a two component hardening system, the composition comprises two components which forms the vulcanized silicone material comprises of part A which comprising of a dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col. 3, lines 55 to end) as well as a trimethyl endblocked polysiloxane which contains a hydride (Col 4, lines 5-15) and part B which comprises a platinum catalyst (Col.4, lines 25-40) and the same dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col 4, lines 20-25).

Claim 3: The limitations of instant claims 1 and 2 are addressed supra. While not explicitly stated, the silicone molding material of the '096 prior art is cross-linked. The vulcanized silicone material comprises of part A which comprising of a dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col. 3, lines 55 to end) as well as a trimethyl endblocked polysiloxane which contains a hydride (Col 4, lines 5-15) and part B which comprises a platinum catalyst (Col.4, lines 25-40) and the same dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col 4, lines 20-25) . As evidenced by the '400 prior art, the reactive hydride (Si-H) group of the trimethyl endblocked polysiloxane with (Col 1, lines 40-45) acts as a cross-linking agent. The dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col. 3, lines 55 to end) is a diorganopolysiloxane. With regard to the reactive silicone base being composed of

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“mainly” diorganopolysiloxane, the silicone material of the ‘096 prior art comprises of 200 parts same dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Columns 3 and 4) and only 4 parts of the trimethyl endblocked polysiloxane (Col 4, lines 5-15), thus the silicone base comprises mainly of the diorganopolysiloxane.

Claim 5: The limitations of instant claim 1 are addressed supra. The examiner has analyzed instant claim 5 to determine whether the recited purposed or intended use results in a structural difference between the recited composition and the prior art. The examiner as demonstrated that the ‘096 prior art composition is capable of performing the intended use and thus meets the limitations of the claim. As discussed supra, the ear molds of are taken of the human ear canal (Questions, page 7 paragraph 4). The composition of the ‘096 prior art is applied to the ear canal of patient (Col. 4, lines 43-50) who is an individual with impaired hearing (abstract), demonstrating that the patient is a human. Humans (i.e. *Homo sapiens*) are scientifically classified in the Kingdom Animalia demonstrating that humans are animals.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No 4,412,096 (hereinafter '096) by Edgerton *et al.* and U.S Patent No. 5360858 (hereinafter '858) by Fujiki *et al.*, US Patent No. 4714739 (hereinafter '739) by Arkles, and US Patent No. 5674966 (hereinafter '966) by McDermott.

Claims 1-3: The limitations of instant claims 1-3 are addressed supra.

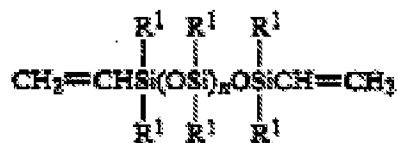
Claim 4: The limitations of instant claims 1-3 are addressed supra. The '096 prior art teaches a composition which comprises of a silicone material which comprises a silicone base diorganopolysiloxane with 2 vinyl groups [dimethyl vinyl-chain stopped polydimethyl siloxane copolymer (Col. 3, lines 55 to end)] and trimethyl endblocked polysiloxane which contains a hydride (Col 4, lines 5-15). The examiner notes that the trimethyl endblocked polysiloxane maximally contains 30 hydrides which would be available for cross linking (Col 4, lines 5-15).

The '096 prior art does not teach a hydrogenated diorganopolysiloxane which contains at least two Si-H groups in the molecule.

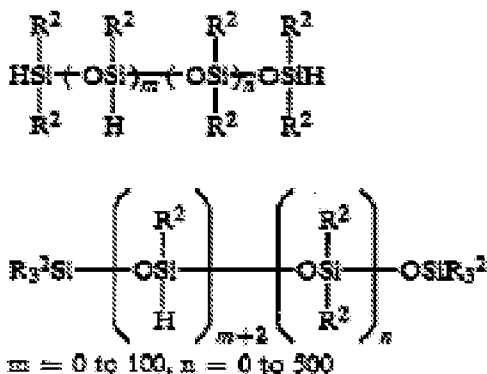
The '858 prior art teaches a silicone rubber composition. Similar to the composition of the '096 prior art, the silicone rubber composition of the '858 prior art comprises a platinum catalyst and a diorganopolysiloxane containing at least two alkylenyl groups in a molecule (Col 2, lines 20-30). Use of vinyl as the two terminal

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groups is explicitly taught in the examples, with the following molecule depicted (Col 2, lines 55-65):



Use of a diorganohydrogenpolysiloxane which cross-links reacts with the above component is specifically taught (Col 3, lines 10-20). It is further taught that the diorganohydrogenpolysiloxane cross-linker should have at least two hydrogen atoms directly attached to silicon atoms in the molecule (Col 3 lines 15-22). The '858 prior art specifically teaches the following molecules as non-limiting examples (Col. 3, lines 35-50):



The examiner notes that in the above two examples, a maximum of 100 to 102 hydrides are available for crosslinking.

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The '739 prior art teaches silicone hydride polymers are not as stable as the silicone vinyl polymers. The simplest solution is to maintain hydride levels higher than stoichiometric requirements (Col. 4, lines 40-50).

The '966 prior art teaches that inhibition of diffusion through cross-linking requires that a molar excess of hydride to alkenyl will improve the physical of a given formulation relative to those formulations where the two reactants are present in strict molar equivalence (Col 12, lines 63 to end; Col 13, lines 1-7).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made to optimize the silicone rubber composition taught by the '096 prior art through substitution of the trimethyl endblocked polysiloxane cross-linker with the diorganohydrogenpolysiloxane cross-linker taught by the '858 prior art. One would have been motivated to do so in order to optimize the cross-linking (i.e. curing) of the silicone material of the '096 prior art through utilization of a cross-linker with more available hydride groups. Use of the cross-linker taught by the '858 prior art would continue to provide available hydride groups to the reactive vinyl groups for cross linking as the silicon material becomes more "solid" and diffusion becomes limited. Use of the cross-linker taught by the '858 prior art would also be desirable because the excess of hydride groups on the cross linker, would still permit cross-linking with vinyl groups, although some hydride groups may have been lost to the environment through unwanted reactions with contaminants (i.e. instability). One of ordinary skill in the art would have been further motivated to use the cross-linker taught by the '858 prior art because the cross linker had been used with success in a similar system.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LORI MATTISON whose telephone number is (571)270-5866. The examiner can normally be reached on 8am-6pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. M./
Examiner, Art Unit 1619

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615